

REMARKS:

The claims in the application remain 34, 36-55, 57-60 and 62-74.

Favorable reconsideration of the application is respectfully requested.

All claims have been rejected under 35 U.S.C. §103 as obvious over the combination of European Appln. No. 0956869 (Soe II) in view of the U.S. patents to Colombo et al, Edwardson et al and Sugitachi et al. More particularly, the Examiner acknowledges reliance upon hindsight reasoning at the bottom of page 5 of the Final Office Action, it then being stated on page 6 of the Final Office Action the products in the cited references presumably are constructed from cellulose fibers used for wounding healing treatment. Thus, it is maintained the collective prior art discloses a product reading on the claimed limitations and therefore functioning in the same manner as claimed.

Accordingly, the Examiner asserts the burden of proving patentability now shifts to Applicants to clearly distinguish between the claimed invention and collective prior art. In this regard, the Examiner explicitly states, at the top of page 5 of the Final Office Action:

[T]he features embodied in the Claims 67-74 ,
fibrinomer absorptivity, maximum platelet agglutination rate,
agglutination percentage, adhered cell count, and mean
hemostatis time, would be inherent to the disclosure of the
prior art [emphasis added].

Firstly, it is respectfully submitted inherency must be absolutely certain and not a mere possibility: In re Oelrich (CCPA 1981) 666 F.2d 578, 212 USPQ 323; Ex part Keith et al. (POBA 1966) 154 USPQ 320. As was stated in the CCPA decision Hansgirk v. Kimmer (CCPA 1939) 102 F.2d 212, 40 USPQ 665 more than 60 years ago:

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient [emphasis added].

The question of inherency arises in anticipatory rejections under 35 U.S.C. §102, not obviousness-type rejections under 35 U.S.C. §103. The fact the Examiner has resorted to a combination of four references clearly substantiates the claimed features are not inherently disclosed in any one of these four references which could, *arguendo*, be combined in any of a variety of possible fashions.

Furthermore, attention is respectfully called to an article written by Irving N. Feit and Christina L. Warrick entitled "Inherency in Patent Law" in the January 2003 issue of the Journal of the Patent and Trademark Office Society (JPTOS vol. 85, no. 1, January 2003, pp. 5-21). The following conclusion is posited by the authors on page 21 (the last page) of this article:

The authors believe all of the cases described above, [case citations deleted] can be reconciled. The cases appear to be consistent with the proposition that the ultimate standard for determining whether a claimed element is inherent in the prior art is the objective understanding of a person having ordinary skill in the art [emphasis added].

To this end, and also addressing the Examiner's request supra to clearly distinguish the claimed invention from what is collectively disclosed in the prior art, attention is respectfully called to the enclosed Declaration under 37 C.F.R. § 1.132 by joint inventor Yoshio Jo, in favor of patentability. The contents of this Declaration will now be discussed.

In paragraph 3 of his Declaration, Mr. Jo states the present invention provides distinct, important improvement in manufacturing a soluble, trauma-healing hemostatic cellulose fiber containing (three types of) coagulation proteins and which rapidly dissolves when contacting blood to provide excellent hemostatic effect. Three examples (1)-(3) of the manner of activity of the inventive fiber are set forth in paragraph 3 of his Declaration, with other properties also set forth in paragraph 4 thereof.

It is explicitly stated by Mr. Jo in paragraph 5 of his Declaration the testing set forth in the Tables and Figures of the present application was carried out under his direction and control. This testing is explicitly addressed in paragraphs 6-11 of his Declaration. To summarize, degree of hydroxyl group substitution is effectively controlled in the inventive fiber, which is then completely soluble in water and saline. Improved fibrin monomer absorptivity, platelet agglutination activity, adhered cell count and reduced hemostasis time is attained with the inventive fiber over hemostatic fiber containing no protein or the total absence of fiber altogether.

Therefore, the testing set forth in the present application compares the closest prior art to the claimed invention. In fact, hemostatic fiber containing no protein failed to improve platelet agglutination over the total absence of hemostatic fiber altogether. Therefore, if anything, one skilled in the art would be lead away from even looking to such fiber to improve hemostasis, hence away from the invention claimed herein. Accordingly, Mr. Jo concludes, in paragraph 12 of his Declaration, the improvements documented by this testing are surprising to him and not at all expected by the level of skill in the art available to him.

Mr. Jo then addresses the individual references in paragraphs 14-17 of his Declaration. Firstly, Mr. Jo points out in paragraph 14 Soe II fail to show preparation of a cellulose fiber, much less a fiber imparted with the coagulation proteins in the manner of the present invention. The Examiner has even acknowledged at the top of page 3 of the Final Office Action, Soe II fails to teach a fiber hydroxylated to the degree claimed and combined with coagulation proteins in the manner of the claimed invention.

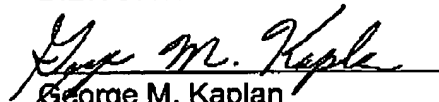
Mr. Jo then points out in paragraph 15 Colombo et al prepare hydroinsoluble carboxy-alkyl cellulose for use in towels, napkins, bandages, etc., thus clearly leading away from the presently claimed invention and documented improvements. Attention is respectfully called to independent Claim 34 which recites a soluble trauma-healing hemostatic cellulose fiber. By the same token, Mr. Jo points out, in paragraph 17, Sugitachi et al also disclose fixing a blood coagulation factor to sutures, pads, bandages, etc. which are also not intended to be water-soluble, hence also teaching away from the claimed invention.

Edwardson et al are dismissed by Mr. Jo in paragraph 16 of his Declaration. In this regard, Mr. Jo points out none of these applied references teaches or suggests preparing the inventive fiber with the combination of all three coagulation proteins as claimed (please see independent Claim 34). Therefore, Mr. Jo concludes, in paragraph 18 of his Declaration, even if the teachings of all four references are combined, such a combined teaching still fails to suggest to him, one skilled in the art, the surprising advantages attained by the claimed invention as documented in the testing set forth in the present application.

Therefore, it is respectfully submitted the proof requested by the Examiner at the middle of page 5 and bottom of page 6 of the Final Office Action, has indeed been provided by Applicants. Accordingly, in view of the forgoing Remarks and accompanying Declaration executed by Mr. Jo, it is respectfully submitted all claims pending herein are in condition for allowance. Please contact the undersigned attorney should there be any questions. A petition for an automatic one month extension of time is enclosed, together with authorization to charge the \$110 petition fee to Deposit Account No. 04-1121.

Early favorable action is earnestly solicited.

Respectfully submitted,
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Response under 37 C.F.R. 1.116 -
Expedited Procedure - Examining
Group Art Unit 1615

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Jo et al.

Examiner: Oh, Simon

Serial No.: 10/069,561

Group Art No. 1615

Filed: October 22, 2001

Docket: 763-29

For: HEMOSTATIC SOLUBLE
CELLULOSE...

Dated: May 27, 2004

MAIL STOP: AF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

AMENDMENT TRANSMITTAL FORM

Transmitted herewith is an amendment in the above-identified application.

☐ Small entity status of this application under 37 C.F.R. §§1.9 and 1.27 has been established by a verified statement previously submitted.

☐ A verified statement to establish small entity under 37 C.F.R. §§1.9 and 1.27 is enclosed.

☒ No additional fee is required.

For	Claims Remaining After Amendment	Highest No. Previously Paid For	Present Extra	Rate (Small Entity)	Addit. Fee	Rate	Addit. Fee
TOTAL CLAIMS*	38	38	0	x 9 =	\$0	x 18 =	\$0
INDEPENDENT CLAIMS	2	3	0	x 43 =	\$0	x 86 =	\$0
<input type="checkbox"/> First Presentation of Multiple Dep. Claim				145		290	\$0

* If the entry in Col. 1 is less than entry in Col. 2, write "0" in Col. 3.

** If the "Highest No. Previously Paid for" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The Highest No. Previously Paid For (Total or Indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

CERTIFICATE OF FACSIMILE


I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office (1-703-872-9306) on the date shown below.

Dated: May 27, 2004



- ☐ Please charge Deposit Account No. 04-1121 in the amount of \$____. Two (2) copies of this sheet are enclosed.
- ☐ A check in the amount of \$__ is enclosed.
- ☒ Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §§1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 04-1121. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 04-1121 therefor. A DUPLICATE OF THIS SHEET IS ENCLOSED.

Respectfully submitted,


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